

**QUESTIONS AND ANSWERS ON MRP & DCP AND
EU ENLARGEMENT**

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This document was developed to address the enlargement of the EU on 1st May 2004, it was further revised, where appropriate, to consider the accession of Romania and Bulgaria to the EU on 1st January 2007 and the accession of Croatia on 1st July 2013.

In this document, the term ‘old Member States’ means the all MSs pertaining to the EU prior to the accession of new countries, as well as Norway, Iceland and Liechtenstein. The term ‘new Member States’ means the new acceding countries.

Abbreviations used:

CMS	- Concerned Member State
CADREAC	- Collaboration Agreement between Drug Regulatory Authorities in EU Associated Countries
DCP	- Decentralised Procedure
EU	- European Union
MA	- Marketing Authorisation
MRP	- Mutual Recognition Procedure
MS	- Member State
RMS	- Reference Member State
SmPC	- summary of Product Characteristics
PL	- Package Leaflet

Question 1

Where can guidance and recommendations in relation to MRP and EU enlargement be found?

Answer:

They can be found in the document: [Phasing-in EU procedures: MRP and referrals](#).

Question 2

When can the new MSs be included in a MRP or DCP?

Answer:

New MSs can be included in an MRP or DCP from the date of accession. Applications for Mutual Recognition or Decentralised Procedures can be submitted as of the date of accession to the new MSs.

Question 3

Do the acceding countries have the same rights as old Member States in terms of MRP and DCP?

Answer:

Acceding MSs have the same rights as the old MSs as of the date of their accession. This applies also to the MRP and DCP, where they can act as RMS or CMS.

Question 4

What is the derogation clause contained in the Accession Treaties of some of the acceding countries and where can information about it be found?

Which countries have a derogation clause in their Accession Treaty?

Answer:

By way of derogation from the requirements of quality, safety and efficacy laid down in Directive 2001/83/EC, MAs for some pharmaceutical products in those countries which have a transitional period issued under the law of the country in question prior to their accession, shall remain valid until they are renewed in compliance with the *acquis communautaire* and in accordance with the timeframe set out, or until the end of the derogation period, whichever is the earlier. Notwithstanding the provisions of Title III, Chapter 4, of the Directive, MAs covered by this derogation shall not benefit from Mutual Recognition in the Member States until the corresponding dossiers are in compliance with the *acquis communautaire* (Directive 2001/83/EC). The lists of products and the set out timeframes are published in the appendix of annexes V to XIV of art. 24, title I (Temporary provisions) of the Act of Accession.

Croatia joining on 1st July 2013 has a derogation clause, with a four-year transition period.

Question 5

Will the MA of Mutual Recognition products be recognised by the new MSs which are to join the EU?

Answer:

For products authorised in the old MSs via the MRP or DCP, a MA application within the framework of the Mutual Recognition Procedure has to be submitted to the national competent authorities of the new MSs. Only Commission Decisions concerning products authorised by the centralised procedure will extend automatically to the territory of the new MSs which are to join the EU.

Question 6

Can companies based in Norway, Iceland and Lichtenstein apply for MAs in new MSs?

Answer:

Before enlargement national legislation applies. Therefore, the competent authority of a new MS may ask/ advise (depends on current legislation of each country) the applicant to be based in the new MS or in the Union. After enlargement, the common rules of Mutual Recognition will apply to all the Member States (old and new) and applications from companies based in Norway, Iceland and Lichtenstein will be accepted.

Question 7

What will happen with pending national applications in the Member States for products already approved/pending in another Member State at the date of accession?

Answer:

Articles 17(2) and 18 of Directive 2001/83/EC are applicable in this situation. According to Article 17(2) of Directive 2001/83/EC, where a Member State (new or old) notes at the date of accession that another marketing authorisation application for the same medicinal product is being examined in another Member State, the Member State concerned shall decline to assess the application and advise the Applicant that Articles 27 to 39 of Directive 2001/83/EC apply. The Member State, which has already started the examination, will normally be the future RMS.

See also Q&A 3 of the Questions and Answers on Applications for MA published on this website <http://www.hma.eu/227.html>

As per Article 18, in cases where the same medicinal product is already authorised via a national, mutual recognition or decentralised procedure in a Member State at the date of accession, the MS concerned shall reject the application (unless it was submitted via the Mutual Recognition Procedure) and will inform the MS where the product has been authorised.

As stated under 3.2, chapter 2 of Volume 2A of NtA, differences between the SmPC, PL and labelling approved in one MS and the SmPC, PL and labelling submitted in another MS do not automatically prevent the latter from a MRP. If these differences have no therapeutic implications (no difference in the efficacy and safety profile), i.e. both products have the same qualitative and quantitative composition in active substances (i.e. the same strength) and the same pharmaceutical form, they have to be considered as being the same and the MRP has to be followed.

See also Q&A 4 of the Questions and Answers on Applications for MA published on this website: <http://www.hma.eu/227.html>

Question 8

How should pending applications in old and new MSs be progressed where there is also an authorised product on a transitional list? The particular situation is that the authorised medicinal product is subject to a derogation clause. Can the applicant continue with the pending national applications or should they select one of the MSs with a pending application and ask them to be RMS?

Answer:

The authorised product on the transitional list cannot be the subject of a MRP until the dossier is in line with Directive 2001/83/EC.

Once compliance with Community law has been achieved, the authorisation does not rely anymore on the derogation and can benefit from mutual recognition. As of the date of accession, Article 17(2) of Directive 2001/83/EC applies, i.e., the Member States where the applications are pending shall decline to assess the applications and advise the Applicant that Articles 27 to 39 of Directive 2001/83/EC apply.

Question 9 – Deleted in December 2012.

Is it possible for pending applications in new MSs at the date of accession for medicinal products with a well-established use to continue national independent procedures?

Answer:

~~According to the Commission communication on the Community marketing authorisation procedures for medicinal products 98/C 229/03, national independent procedures may still be followed in the case of a medicinal product with a well-established use (bibliographical applications), provided that the two following conditions are fulfilled:~~

- ~~• The well-established use is based on data referring to an existing group of products with different SmPCs in the Member States, and~~
- ~~• No Community harmonisation of the use of the constituent(s) of the said product exists.~~

~~Community harmonisation of the use of the constituent exists if the constituent of the said product is the constituent:~~

- ~~• Of a product which underwent the ex-concertation procedure within the scope of application of Directive 87/22/EEC,~~
- ~~• Of a product involved in referral procedure under Article 30 of Directive 2001/83/EC, as amended, or~~
- ~~• Involved in referral procedure under Article 31 of Directive 2001/83/EC, as amended.~~

~~Community harmonisation also exists in the case of a medicinal product authorised by MRP. Therefore, in these cases a product cannot be authorised by national independent procedure in further Member States.~~

Question 10

Where pending applications in new MSs are rejected after the date of accession, how is it intended to regulate the financial contribution of fees paid for these applications?

Answer:

The fees for applications are a purely national issue, for which the competent authorities in the new MSs are solely responsible.

Question 11

What are the simplified CADREAC and nCADREAC procedures?

Answer:

The so-called ‘simplified CADREAC’ and ‘nCADREAC’ procedures have been adopted by CADREAC Annual Assembly on April 2001 in Prague and on March 2004 in Bucharest, respectively. The purpose of the adopted documents is to describe a licensing procedure which can be used by any CADREAC drug regulatory authority before the date of accession for granting a MA to a medicinal product which has been authorised in the old MSs, following a Mutual Recognition Procedure (MRP). For further guidance see the document: ‘Procedure on the granting of Marketing

Authorisations by new CADREAC (nCADREAC) drug regulatory authorities for medicinal products for human use already authorised in EU Member States following the mutual recognition procedure and the variations and renewals of such Marketing Authorisations’. [Procedure on the granting of Marketing Authorisations by new CADREAC](#)

Question 12

Is the use of the simplified nCADREAC procedure mandatory?

Answer:

No, it is not mandatory either for the applicant or for the nCADREAC drug regulatory authority. See the document ‘Procedure on the granting of Marketing Authorisations by new CADREAC (nCADREAC) drug regulatory authorities for medicinal products for human use already authorised in EU Member States following the mutual recognition procedure and the variations and renewals of such Marketing Authorisations’, section “PRINCIPLES”. [Procedure on the granting of Marketing Authorisations by new CADREAC](#)

Question 13

How could an applicant benefit from having a product authorised in new MSs via the simplified CADREAC/nCADREAC procedure?

Answer:

The main benefit of having used the simplified CADREAC/nCADREAC procedure is the possibility to conduct a repeat use MRP within a shorter timeframe (30 days) if the MAH wishes to add a national MA granted before the date of accession into an existing MRP. All MSs involved in the procedure have to agree with the shorter timeframe. Agreement means that the new MS can accept the current SmPC, labelling and package leaflet in the repeat use without any comments and is therefore prepared to grant a marketing authorisation.

Applicants are advised to discuss with the RMS in advance of the submission of the MRP. See also the [Procedural Advice on Repeat Use](#).

Question 14

Products approved in new MSs through the simplified CADREAC/nCADREAC procedure may have different product names or have different pack sizes, or assembly and batch release sites and/or MAH from those approved in the old MSs. If these products are the subject of a shorter 30-day repeat use MRP, how will these differences be handled?

Answer:

Different product names in different MSs are acceptable within a MRP. Additional pack sizes should be added to the MR-SmPC either before or after the repeat use procedure. Additional assembly or batch-release sites may not be included in the repeat use MRP but should be added by the appropriate variation after the procedure is

finished. In order to ensure supply continuity, it should be noted that the current MA in the new MSs does not need to be withdrawn when a repeat use MRP is started, so that batches may be supplied under that MA during the MRP. When the product is approved under the MRP, the original MA may either be withdrawn or the two MAs may have different names. It is not possible to have independent MAHs being part of the same MR/DC procedure.

Question 15

Is it possible, within a repeat use MRP, to complete a variation to a MA granted in the new MSs via the simplified CADREAC/nCADREAC procedure, if the variation is pending in the CMSs at the time of the MRP?

Answer:

The dossier should include the pending variation application and this should be explained in the covering letter. Inclusion of pending variations may mean that it is not possible to complete the MRP according to the shortened 30-day procedure as outlined in the [Procedural Advice on Repeat Use](#).

Question 16

If there are simplified nCADREAC procedures still pending in new MSs on the date of accession, is it possible to have a shorter 30-day administrative procedure for them without having to do a repeat use procedure

Answer:

No, if the products are to be brought into MR, then a repeat use MRP must be started.

Question 17

What is the documentation to be submitted for simplified MRP following CADREAC/nCADREAC procedures?

Answer:

The principle of CADREAC/nCADREAC procedure was the submission of identical dossier and identical post-authorisation maintenance as in the MRP, as well as the submission of all assessment reports generated within DCP/MRP. Therefore the documentation to be submitted by the applicant can be limited to the following:

- Application form
- Declaration of MAH that the dossier already submitted in the new CMS is identical to the current dossier in RMS
- Proposed dates for common MRP renewal and PSURs submissions
- If an application for a variation to the MA of the product concerned is pending in the new CMS at the time of repeat use MRP, the explanation should be provided in the covering letter and acceptability of processing the repeat use procedure in 30 days should be pre-discussed with the new CMS

The RMS should send to the new CMSs the following:

- Copy of current product information
- List of all variations and renewals approved in MRP for the product concerned
- The common renewal date

If needed, the new CMS can request the RMS to send any missing variation report or an updated assessment report before the procedure can start.

Question 18

Can the shorter-timeframe MRP be used for products already harmonised in the old MSs, through referrals or through an MRP covering all EEA countries?

Answer:

It is always possible to have a procedure which is shorter than 90 days if CMSs do not have any objections. In all cases, there must be an MR procedure and an application submitted to the new MSs. It should be noted that following a referral, the product information may be harmonised but not the dossiers.

If the proposed product information (and the dossier) is the same as that (already harmonised) in the old MSs, this should be stated in the application to inform the CMSs.

Question 19

If the dossier and product information of a product in new MSs is harmonised with the dossier and product information of an MR product, can a repeat use MRP benefit from a shorter-30-day timetable? If there are differences, e.g., in pack sizes or manufacturing sites, can these be included in the application?

Answer:

The MRP timetable can be shorter if all CMSs agree. Companies are advised to discuss their proposals with the RMS before submission of the application. Any differences in the dossier should be handled as mentioned in the answer to question 14.

Question 20

Will it be possible to register ex-concertation products in new MSs through a repeat use MR procedure?

Answer:

A repeat use is allowed if the ex-concertation product is still registered nationally in old MSs.

Question 21

If an ex-concertation product is already authorised nationally in new MSs, would it be possible to use a repeat use to bring the product under the MRP?

Answer:

If the ex-concertation product is still authorised nationally (through MRP) in old MSs, a repeat use procedure is allowed to authorise the product in new MSs through the MRP. However, it can remain as national MAs on the new MSs' markets.

If MAH of the ex-concertation product has chosen to withdraw the national authorisations and to reapply for a Community marketing authorisation under Regulation 2309/93, the national marketing authorisations in new MSs become inapplicable. Please refer to [PERF – Reflection paper on Phasing in EU procedures: MRP and referrals.](#)

Question 22

Will it be possible to export pharmaceuticals manufactured in the new MSs to old MSs immediately after they officially join the EU?

Answer:

MA holders will be allowed to place medicinal products manufactured in the new MSs in other EU Member States provided that the product shall have a valid MA in the Member State where the product is to be placed on the market and that the manufacturing site in question is covered by the MA.

Question 23

Will EU batch release requirements be the same in new MSs as in old MSs?

Answer:

Yes. On accession, the arrangements for batch release (Qualified Persons, manufacturing authorisation, etc.) must be in place in each new MS.

Question 23a

Will a batch release site located in a new MS be accepted in the old MSs from the date of accession? Will it be possible to submit a variation in the old MSs before the accession so that the batch release site is accepted by old MSs on Day 1 of the accession?

Answer:

A batch release site located in a new MS will be accepted in other MSs once the variation to add it to the MA is approved. However, the variations cannot be submitted before the date of accession.

Question 24

After repeat use MRP to new MSs, will the product have the same common renewal date as it has in the old MSs?

Answer:

Yes, the common renewal date already established for the product can be maintained. For further details, please see the ‘CMDh best practice guide on the processing of renewals in the mutual recognition and decentralised procedures’ published on this website.

Question 25

Is there an obligation to use the MRP or DCP for a line extension to a product initially approved through a national procedure in the new MSs, including products approved using the simplified CADREAC/nCADREAC procedure?

Answer:

No, independent national procedures can be used for extensions of authorised medicinal products as far as no a priori harmonisation has been achieved. For further guidance, see also the document [MSs Recommendations on Extension applications in Mutual Recognition and Decentralised Procedures](#).

Question 26

Can a product be the subject of a MRP if it is approved in accessing MS having a derogation clause with a dossier that is on a transitional list and is therefore not in line with the requirements of Directive 2001/83/EC?

Answer:

No, this is not possible. Only dossiers which meet EU requirements can be the subject of a MRP. See also Q&A No. 4 within this document.

Question 27

How can an applicant combine into one MRP a MS with a transitional period and one without a transitional period?

Answer:

The applicant should make a repeat use MRP application into both CMSs, using the EU dossier already approved in the RMS.

Question 28

Can it be confirmed that the deadline for preparing/updating the assessment report is 90 days from the official request made by the applicant?

Answer:

For steps to follow to obtain an assessment report, please consult Chapter 2 of Volume 2A of the Notice to Applicants. It should be noted that the request for an assessment report or an update of an assessment report occurs after any update of the dossier which may be necessary before starting an MRP. After the dossier has been updated, the applicant makes a formal request to the RMS for an (updated) assessment report, which is provided no later than 90 days after receipt of the request.

Question 29

Are the outcomes of all referrals (i.e. Articles 29, 30, 31 and 107) binding on new MSs?

Answer:

Referral decisions apply only to those MSs addressed in the Decision; they do not apply to MSs not addressed in the Decision or to those MSs which later acceded to the EU. In MSs not directly concerned by the procedure, no immediate actions is necessary since there are no pending applications or MAs for the medicinal product in question. However, these MSs as addressees of the decision, should consider whether any action is appropriate as regards products authorised by them and should take the decision into account in any future regulatory action. Please see Notice to Applicants, Volume 2, Chapter 3 and PERF – [Reflection Paper on Phasing in EU procedures: MRP and Referrals](#).

Question 30

If companies wish to apply the outcome of SmPC harmonisation voluntarily in new MSs, which procedure should they use?

Answer:

Voluntary harmonisation is recommended. The procedure to be used for national marketing authorisations in new MSs depends on the national legislation for variations in each new MS until Regulation (EC) No 1234/2008 applies to purely national medicinal products (4th August 2013).

Question 31

How will the data exclusivity of reference products authorised in the accessing countries be counted after their EU accession? If the MA is in line with Directive 2001/83/EC will the years for data exclusivity be counted from the first national authorisation even if before the accession? What if the reference product authorised by national procedure is not in line with Directive 2001/83/EC?

Answer:

See question no. 6 in [Question and Answers on Generics](#).

Question 32

What will happen with generic medicinal products authorised nationally once these MSs have joined the EU: will the MAs granted for these products have to be withdrawn if no more than 8 years has elapsed?

Answer:

Marketing Authorisation granted for generic medicinal products authorised before the accession based on the previously national legislation will still be valid after EU accession.

Question 33

*Can a MA authorisation granted after completion of a repeat use MRP coexist with a national MA granted to the same applicant before the accession and brought in line with the *acquis communautaire*? Can both products have different names even if the dossiers are identical? What if the applicant wishes to have the same name for these two products?*

Answer:

When the product is approved under the MRP, the original national MA may either be withdrawn or the two MA may coexist. Whether the same name can be used for coexisting MRP and nationally authorised products will depend on the national legislation. For the sake of clarity, it is recommended to replace the previous national marketing authorisation with the marketing authorisation granted via MRP.

Question 34

*After accession, is it possible to start a DCP based on an upgraded dossier with a new MS as RMS while keeping the national MA based on a dossier which is not in line with the *acquis communautaire* for the same medicinal product (provided the transition period foreseen in the Accession Treaty has not expired)?*

If yes, can the name of the products authorised by these two procedures (national procedure prior to the accession and DCP procedure after the accession) be the same? What will happen when the MAH will upgrade the dossier for the nationally authorised product: will the national MA have to be withdrawn once the DCP procedure is finalised and a new national MA is granted?

Answer:

A DCP procedure based on the upgraded dossier can be started while keeping the national authorisation valid. Nevertheless, the applicant shall be advised to submit the upgraded dossier to the National Competent Authority at the time the application for DCP starts. Whether the same name can be used for coexisting DCP and nationally authorised products will depend on the national legislation.

Question 35

If a medicinal product is authorised through national procedure in a MS before EU accession and the same product is also authorised in at least one EU MS, will it be mandatory to include this product into a MRP procedure after accession or will this be decided by MAH?

Answer:

The fact that the same medicinal product is authorised in one of the EU countries and was authorised in a new MS prior to the accession, does not automatically trigger the start of a MRP procedure.

Question 36

Is it mandatory for medicinal products authorised through nCADREAC procedure in accessing MS to be included into a repeat use MRP after the accession of this MS, or can they remain authorised through national procedure?

Answer:

It is not mandatory to start a repeat use procedure for products authorised through nCADREAC. After the accession, NCA will continue to independently assess all new documentation for these products if they remain authorised nationally.